# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**64164**

# APPROVAL LETTER

AADA 64-155 (375 mg base/5 mL)
64-164 (250 mg base/5 mL)
64-165 (187 mg base/5 mL)
64-166 (125 mg base/5 mL)

OCT 2 1997

Ranbaxy Pharmaceuticals Inc.
U.S. Agent for: Ranbaxy Laboratories Limited
Attention: Jim Sibert
4600 Marriott Drive
Suite 100
Raleigh, NC 27612

Dear Sir:

This is in reference to your abbreviated antibiotic applications dated July 7, 1995 (AADA 64-155) and September 27, 1995 (AADA 64-164, 64-165, and 64-166), submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act, for Cefaclor for Oral Suspension, USP.

Reference is also made to your amendments dated May 28, and September 4, 1997.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Cefaclor for Oral Suspension, USP 375 mg/5 mL, 250 mg/5 mL, 187 mg/5 mL, and 125 mg/5 mL to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Ceclor® for Oral Suspension 375 mg/5 mL, 250 mg/5 mL, 187 mg/5 mL, and 125 mg/5 mL, respectively, of Eli Lilly and Company).

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require approved supplemental applications before the changes may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of these drugs.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

10/2/97

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: AADA 64-155, 64-164, 64-165, 64-166
Division File
FIELD COPY
HFD-610/JPhillips
HFD-92
HFD-210/B.Poole

APPROVAL